K110259

ARCHITEX™ Space Maintenance System
510(k) Summary

APR 13 2011

January 2011

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
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Contact: **Kelly Davidson**
Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:**
ARCHITEX™ Space Maintenance System

III. **Classification Name(s):** Implants, Endosseous, Root-Form
21 CFR 872.4760;
Product Code(s): DZE, JEY

IV. **Description:**

The ARCHITEX™ Space Maintenance System is a comprehensive, all-inclusive system which contains a variety of implants designed to temporarily reconstruct bony deficiencies common to the oral cavity that are not intrinsic to the stability of the bony structure. Bony deficiencies may be naturally occurring osseous defects, surgically created osseous defects, or osseous defects created from traumatic injury to the bone.

The system contains a porous titanium mesh, titanium alloy mesh fixation screws (1.2 mm major thread diameter in 4mm, 6 mm, 8 mm, 10 mm, 12 mm, 14 mm lengths and 1.4 mm major thread diameter in 3 mm, 5 mm, and 7 mm lengths), titanium alloy tenting screws (1.2 mm and 1.4 mm major thread diameters in 8 mm, 10 mm, 12 mm, and 14 mm lengths), and titanium alloy socket preservation screws (3/4 head geometry with 1.2 mm and 1.4 mm major thread diameters in 18 mm and 20 mm lengths; 4/5 and 5/6 head geometries with 1.2 mm major thread diameter in 14 mm, 16 mm, 18 mm , 20 mm lengths and 1.4 mm major thread diameter in 18 mm and 20 mm lengths). When used as indicated, this system provides a semi-protected space to stabilize, support, and protect bone graft (autograft, autograft extenders, allograft, and bone void fillers) by minimizing soft-tissue collapse into the graft recipient site. The ARCHITEX™ Space Maintenance System includes a selection of Socket Preservation screws which are designed to aid in extraction socket grafting while simultaneously supporting the original gingival margins and papilla.

The ARCHITEX™ Space Maintenance System components are fabricated from medical grade stainless steel and medical grade titanium or titanium alloy. Medical grade titanium and titanium alloy may be used together. The subject implants components will be manufactured from medical grade titanium per ASTM F67-06 (2006) and Ti-6Al-4V ELI Alloy per ASTM F136-08el (2008).

Additionally, the instruments components are manufactured from stainless steel per ASTM F899-09.

The purpose of this 510(k) application is to seek marketing clearance for additional implant sizes to the family of Socket Preservation Screws to extend the product line for the ARCHITEX™ Space Maintenance System. Also included in the application is the dimensional modification to the diameter of the mesh fixation screws (Hex Self Drilling Screws) from the previously cleared implants in K100779. The device description in the IFU was also amended, which removed the implant sizes, the list of class I exempt placement instruments that can be used, the screw caddy and sterilization tray. Refer to the labeling section below for further details to the IFU amendments.

V. Indications for Use:

The ARCHITEX™ Space Maintenance System is indicated for use as temporary implants to stabilize and support autograft, autograft extenders, allograft, and bone void fillers and/or fractured bone segments with or without bone plates or titanium mesh in bony defects of oral maxillofacial anatomy.

VI. Identification of the Legally Marketed Predicate Devices Use to Claim Substantial Equivalence:

The design features, materials, and indications for use of the ARCHITEX™ Space Maintenance System is substantially equivalent to the predicates listed in the Table 1 below.

TABLE 1. Identification of the Legally Marketed Predicate Devices Use to Claim Substantial Equivalence

ARCHITEX™ Implant	Predicate	Substantial equivalence
Hex Self Drilling crews	ACE Tru Screw™ (K080074)	Geometrically, materially, and mechanically equivalent. Bone pull-out strength and screw subsidence equivalent to predicate.
Socket Preservation Screws	ARCHITEX™ Space Maintenance (K100779)	Bone interfacing portion of screw geometrically, materially, and mechanically equivalent. Bone pull-out strength and screw subsidence equivalent to predicate Head portion of screw geometrically, materially, and mechanically equivalent to predicate abutments

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VII. Brief Discussion of the Non-Clinical Tests Submitted

For a determination of substantial equivalence, the following analysis and bench performance tests were performed on Subject Devices and Predicate Devices:

- Static Removal Torque; Testing in accordance with ASTM F543-02.
- Static Axial Pullout testing; Testing in accordance with ASTM F543-02
- Static Axial Pullout mesh screw; Testing in accordance with ASTM F543-02

VIII. Conclusions Drawn from the Non-Clinical Tests

Results of the testing have demonstrated that ARCHITEX™ Space Maintenance System implants are equivalent to itself and the ACE Tru Screw™ implants tested. When compared with predicate devices, results of bench performance testing indicated all acceptance criteria were met, and demonstrated the subject hex self drilling screws and socket preservation screws are equivalent. The conclusions drawn from the performance testing, along with the intended use of the subject devices demonstrate that the ARCHITEX™ Space Maintenance System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Kelly Davidson
Regulatory Affairs Specialist
Medtronic Sofamor Danek USA, Incorporated
1800 Pyramid Place
Memphis, Tennessee 38132

APR 13 2011

Re: K110259
Trade/Device Name: ARCHITEX™ Space Maintenance System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY and DZE
Dated: January 24, 2011
Received: January 28, 2011

Dear Ms. Davidson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K110259

Device Name: ARCHITEX™ Space Maintenance System

Indications for Use:
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __Yes_X__OR Over-The-Counter Use __No___
Per 21 CFR 801.109

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K110259